THIS A MODIFIED SAMPLE DOD SINGLE PROJECT ASSURANCE (SPA) FOR AN INSTITUTION UTILIZING THE INSTITUTIONAL REVIEW BOARD (IRB) OF ANOTHER INSTITUTION. THE INSTITUTION WITH AN IRB MUST HAVE A MULTIPLE PROJECT ASSURANCE (MPA) ON FILE WITH OPRR OR DOD COMPONENT ACTIVITY, OR MUST SUBMIT A SINGLE PROJECT ASSURANCE (SPA) FOR DOD APPROVAL (Rev June 1998)

_____

(Name of Institution)

Assurance of Compliance with DOD Regulations for Protection of Human Research Subjects

PART 1

(Name of Institution), hereafter known as the "institution" hereby gives assurance that it shall comply with the Department of Defense (DOD) Regulations for the Protection of Human Research Subjects, (DOD Regulation 32 CFR 219, and where applicable, HHS Regulation 45 CFR 46, Subparts B, C and D), and Title 10, United States Code, Section 980 (hereinafter referred to as 10 USC 980) as specified below.

I. Statement of Principles and Policies

A. Ethical Principles

1. This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"). In addition, the requirements set forth in 32 CFR 219 and 10 USC 980 shall be met for all applicable DOD-supported research.

B. Institutional Policy

1. Except for research in which the only involvement of human subjects is in one or more of the categories exempted or waived under 32 CFR 219.101(b) (1-6), and 10 USC 980 this policy is applicable to all research involving human subjects, and all other activities which even in part involve such research, if either:

a. the research is sponsored by this institution, or

b. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or

c. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or

d. the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

2. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects in research covered by this policy.

3. This institution assures that before human subjects are involved in research covered by this policy, proper consideration shall be given to:

   a. the risks to the subject,

   b. the anticipated benefits to the subjects and others,

   c. the importance of the knowledge that may reasonably be expected to result, and

   d. the informed consent process to be employed.

4. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this policy.

5. This institution bears full responsibility for complying with federal, state, or local laws as they may relate to research covered by this policy.

6. This institution encourages and promotes constructive communication among the research administrator, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

7. This institution shall exercise appropriate administrative overview carried out at least annually to ensure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

8. This institution shall consider additional safeguards in research when that research involves prisoners, fetuses, pregnant women, children,

individuals who are ionized as mentally disabled, other potentially vulnerable groups and human in vitro fertilization.

9. This institution shall provide each individual at the institution conducting or reviewing human subject research (e.g. research investigators, department heads, research administrators, research reviewers) with a copy of this statement of Ethical Principles and Institutional Policy.

PART 2

In regard to the Project entitled, "_____ _____", Project Number _____, submitted on behalf of (name of investigator/project director), this institution has complied and shall continue to comply with the requirements of 32 CFR 219, Part 1, and 45 CFR 46 Subparts B, C and D, and 10 USC 980 as specified below.

I. Institutional Review Board (IRB) Review

A. This institution does not have an IRB, but will rely upon the IRB of _____ _____ as its IRB of record. In accordance with the compositional requirements of 32 CFR 219.107, the institution for which this assurance of compliance applies has provided the attached IRB membership roster. This IRB is responsible for the initial and continuing review of this activity and will observe the quorum requirements of 32 CFR 219.108.

B. The cited IRB convened, reviewed and approved this research activity on _____(date)_____.

C. The IRB has determined, in accordance with the criteria found at 32 CFR 219.111, and where applicable, 45 CFR 46 Subparts B, C and D that protections for human research subjects are adequate.

D. The IRB has determined that legally effective informed consent (copy of document must be attached unless reviewed by an IRB of an institution with an OPRR or DOD Component Activity approved Multiple Project Assurance shall be obtained in a manner and method which meets the requirements of 32 CFR 219, and in cases of research involving protected classes of individuals 45 CFR 46, Subparts B, C and D.

E. The IRB shall review, and have the authority to approve, require modification in, or disapprove changes proposed in this research activity.

F. The next scheduled meeting of the IRB for continuing review of this activity shall be (insert date no later than one year from last review). The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or Institutional Official to consider any matter concerned with the rights and welfare of any subject. Documentation of continuing review must be provided to the Human Subjects Protection Division (HSPD) no later than one year from last review date.

G. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 32 CFR 219.115.

H. The IRB shall report promptly to institutional officials and to the HSPD:

a. any serious or continuing noncompliance by investigators with the requirements of the IRB, and

b. any suspension or termination of IRB approval.

I. The IRB shall report promptly to institutional officials and the HSPD any information received concerning:

a. injuries to human subjects,

b. unanticipated problems involving risks to subjects or others, and

c. any changes in this research activity which are reviewed and approved by the IRB.

J. The IRB will comply fully with 10 USC 980 which states: if an individual cannot give his /her own consent, and there is not intent to benefit the subject, (for example, minors) he/she cannot be entered into a study funded by the DOD. This is legally binding and there will be no exceptions.

II. Research Investigator Reporting Responsibilities

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects for complying with all applicable provisions of this Assurance and 32 CFR 219, 45 CFR 46 and 10 USC 980.

B. Research investigators shall report promptly to the IRB and HSPD any

proposed changes in this research activity and the changes shall not be initiated without IRB and HSPD review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. Any change in the investigator or change to the protocol must be reported to the IRB and to HSPD.

C. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others. Any serious and unexpected adverse events(s) must be reported to the IRB and to the HSPD.

III. Institutional Responsibilities:

A. This institution has provided and shall continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.

1. injuries to human subjects,

2. unanticipated problems involving risks to subjects or others, and

3. any changes in this research activity which are reviewed and approved by the IRB and this institution.

B. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the project entitled,"_____ _____".

C. In accordance with the requirements of Section 32 CFR 219.107, this institution has established an IRB as listed in the attached roster. This IRB is responsible for the initial and continuing review of this activity and shall observe the quorum requirements of 32 CFR 219.108.

PART 3

The officials signing below agree that the research entitled, "_____". Project number:_____, will be conducted in accordance with 32 CFR 219 Part 1 and 45 CFR 46 Subparts B, C and D, and 10 USC 980, and subject to the continuing review and stipulations of the IRB. The IRB's institution shall assume responsibility for ensuring required IRB reviews, approvals, and submission of certifications to the HSPD.

I. Endorsement of Institution Without an IRB

Authorized Institutional Official

Signature _____ Date _____
Name and Title _____
Institution Address _____
_____
_____
Phone number _____

II. Endorsement of Institution with Approved Assurance and IRB

A. Name of Institution: _____

Authorized Institutional Official

Signature _____ Date _____
Name and Title _____
Institution Address _____
_____
_____
Phone number _____

B. IRB Chairperson or Designee Certifying IRB Review and Approval

Signature _____ Date _____
Name and Title _____
Institution Address _____
_____
_____
Phone number _____

****

SPACE BELOW FOR DEPARTMENT OF DEFENSE

III. All parts of this Assurance are in compliance with the requirements of Part 219, Title 32 and Part 45, Title 46 of the Code of Federal Regulations and 10 USC 980.

DOD Approving official

Signature _____ Date _____

Name: Ms. Yvonne Higgins, Chief
Address: Human Subjects Protection Division (HSPD)
U.S. Army Medical Research and Materiel Command
504 Scott Street
Fort Detrick, Frederick, MD 21702-5012

Telephone #: 301-619-2165/2166
FAX #: 301-619-7803

ASSURANCE NUMBER: _____*

An application for new or competing support for continuation in which human subjects will be involved will require a new and separate Assurance, unless the activity is exempt under section 32 CFR 219.101 (b).

INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP

NAME OF IRB AGENCY OR COMMAND _____

Address and Phone No Chairperson Only _____
_____
_____
_____

Members' Names First	MI	Last	Highest Degree	Scientific Specialty	Affiliation w/Institution
(1)					
(2)					
(3)					
(4)					

(1) Denotes Chairperson
(2) Denotes IRB member
(3) Denotes IRB alternates
(4) Denotes non-voting IRB attendee (expert or technical expertise)

GENERAL GUIDANCE ON THE USE OF ANOTHER INSTITUTION'S IRB

Each approved Single Project Assurance (SPA) designates an Institutional Review Board (IRB) which is authorized to review and approve cooperative protocols. However, though it may be permissible under 32 CFR 219.114 for an institution to rely on an IRB of another DOD Component Agency approved institution for protocol review, institutions planning such an arrangement should seek prior guidance from HSPD to avoid unnecessary delays. It is in the best interests of institutions to appreciate that review by another's qualified IRB (i.e. HSPD approved) raises questions about membership qualifications that would likely be inherently satisfied when reviews are confined to protocols conducted in the IRB's own institution. Local laws, institutional policies and constraints, professional and community standards, and population differences are examples of pertinent local factors that can influence the setting of research (refer 32 CFR 219.103 (d), 219.107(a), and 219.111(a) (3)). For example, the considered opinion of an IRB of one institution may be blind to information that would alter its decision for another where:

- institutions draw from culturally dissimilar patient populations;

- institutions are located in different states or other geographical subdivision with varied legal or regulatory constraints;

- institutions are not accustomed to each other's services operational policies, constraints, procedures, or commitments; or

- there is uncertain satisfaction of drug control responsibilities, or other FDA requirements.

Apparent efficiencies of such review to avoid perceived duplication of effort may be shortsighted if detached from concomitant review of the setting in which such protocols are to be conducted. Accordingly, reliance on another IRB should not be considered lightly. In spite of a joint willingness between institutions, HSPD may not approve a proposed arrangement if there are circumstances that are not appropriate. Therefore, such plans should include consultation with the HSPD to avoid delays.

Several options for IRB arrangements are available which comply with the letter and intent of both 32 CFR 219.114 and the regulations as a whole.

Institutional sites that are geographically close enough to comfortably contribute membership to a common IRB can share in bearing the costs of operations while simultaneously providing reviews for protocols that may be used by physicians at some or all of the sites. This approach results in one IRB that can be equally cited as their own IRB of record by all sites that contribute to its membership.

A second approach is for one IRB with unique expertise, a legal or administrative preference for involvement, or otherwise to host reviews for other nearby institutional sites with consultant representation from each site present for all initial and continuing reviews of protocols jointly used by these sites. In this approach only the hosting institution has its own IRB. The other sites rely on another's IRB but in such a way as not to defeat the intent of 32 CFR 219.

The most obvious way to fully comply with the regulations is for each site to host its own IRB. An institution that has a standing IRB which is qualified to perform reviews for a specified research activity would be expected to do or justify not doing so before approval would be considered for other options. If a local hospital or research facility exists with a HSPD approved Assurance for the research in question, a second institution may seek permission to rely upon such an IRB when justified. DOD Component agencies should understand the propriety of considering and approving reliance on another's IRB when a plausible case is made apparent. For example, an IRB with a suitably diversified membership might exist at one site to host IRB reviews for another site due to: (1) the cosmopolitan nature of the host site; (2) a wide catchment area from which patients and subjects are referred to it, (3) or reasons as may otherwise be of a compelling and pertinent nature. However, institutional constraints are less easily accounted for between institutions when there is little or no intimate understanding of each other's staff, procedures, policy, practices, and legal issues. Each case deserves individual consideration.

QUESTIONS FOR FOREIGN INSTITUTIONS
NARRATIVE FORMAT FOR PROVIDING AN ASSURANCE OR DETERMING AT LEAST EQUIVALENT PROTECTIONS

1. Please described what principles govern your institution that address protecting the rights and welfare of human subjects in research (for example, Declaration of Helsinki, Council of International Organizations of Medical Sciences Proposed Guidelines).

2. Please describe the institutional review board (IRB; group to protect human subjects) in our institution which can act to review this protocol to protect human subjects. The IRB must be able to address the following concerns: minimal risk to participants; risks to participants and the benefits to participants and other; fair selection of participants; special protections for vulnerable participants; informed consent of participants and how this will be documented ; monitoring data for safety; confidentiality of data.

3. Please describe the membership of the IRB. Who serves as chairperson? Who are the members and their educational degrees and affiliations: (The IRB should include at least five persons: at least one unaffiliated with the institution; one scientist; one non-scientist; both men and women; someone with expertise about the research and who know about the community(ies) from which participants will be drawn.) The principal investigator(s) or family members will not be part of the IRB proceeding or vote.

4. Please describe how the IRB will conduct its initial and continuing review and how the IRB will be informed promptly of any changes contemplated in the protocol.

5. Please describe the informed consent process and provide a copy of both the English version and a copy of its foreign translation of the document (s) to be used to inform the participants about the research and seek their consent.

   If informed consent is not sought or all the required elements are not addressed, please indicate the conditions that the IRB cites that are appropriate to justify waiving consent or specific elements.

6. Please describe how you will maintain the research records (copies of research protocols; minutes; review records; correspondence; IRB members, degrees and affiliations; procedures; statements of new findings to give to participants, etc.).

7. Please describe how the IRB, your institution, and the U.S. Army Medical Research and Material Command will be informed of any serious or

continuing noncompliance with human subjects protections or if the IRB has suspended or withdrawn its approval.

8. Please provide the signature of the institutional official responsible for this project and for making sure that human subjects are protected.

ELEMENTS OF INFORMED CONSENT

In seeking informed consent, the following information should be provided to each subject in the consent form.

1. Title of the study and location (complete address) where the study will be conducted.

2. Name of the principal investigator, and associate (s), if applicable, conducting this study.

3. A statement that the study involves research and a clear explanation of the purpose of the research. In general, the structure of the informed consent should:

    a. Be written in language that is easily understood by the subject.

    b. Use non-medical language that is easily understood by the subject.

    c. Provide a translation of the consent form for subjects enrolled in a study who do not comprehend English. The following statement and information is required on the English language version of the translated consent form:

    "I certify that this is an accurate and true translation." The translator's signature, name, address, phone number, and TELEFAX number should be included.

4. Include a statement clearly indicating the expected duration of the subject's participation (the number of hours, days, etc.).

5. A description of all **procedures** to be followed and identification of any procedures that are experimental. It must be clearly indicated that these procedures are experimental.

    a. Briefly explain the study design relative to what will be done to the subject (in blind or double-blind studies, subjects must be informed that they may receive either the experimental modality or placebo). If a placebo is used, its contents should be described.

    b. Specify what is required of the subject (hospital visits, blood donation, etc.). If blood is to be drawn, (including serum pregnancy tests) the amount(s) to be drawn should be expressed in lay terms.

    c. For procedures/pharmaceuticals/devices which are experimental, (if an IND/IDE has been secured from the FDA), the subject should be advised that the IND/IDE is permission for the study to be undertaken and does not indicate FDA approval for the routine use of the drug/device in the method

proposed in the protocol. If a drug or device covered under an IND/IDE is involved, it must be clearly indicated in the consent form that it is investigational for the purposes of this research.

d. Although a subject may be familiar with procedures, never assume that he/she comprehends everything.

6. A description of any reasonably foreseeable risks or discomforts to the subject. Include risks of pregnancy and possible risks to the fetus, if applicable. It should be clearly indicated if pregnant women will be excluded and/or withdrawn from the study.

a. For studies of potential benefit, describe risks unique to the study; estimate their severity and likelihood; and/or compare their risks with risks which the subject might encounter in the course of his/her daily activities. If similar research has been conducted in the past, describe the incidence of adverse effects or injuries occurring in previous subjects.

b. For studies of no potential benefit to the subject, list all risks which are more than "minimal" (not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine medical tests).

7. A description of any benefits to the subject or to other which may reasonably be expected from the research (mention remuneration, if any). If subjects are to be paid for participation in a research study, those payments should not be unduly large. Lump sum payments where all or most of the payment for study participation is withheld until completion of the study should be avoided since this situation may present questions or coercion of subjects to volunteer for, or continue with, a research study.

8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (e.g., whether treatment is available outside of the protocol).

9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. If should be noted that representatives from the U.S. Army Medical Research and Materiel Command (and, where applicable, the Food and Drug Administration and the U.S. Army Medical Department Center and School) may inspect the records of the research.

10. For U.S. Army Medical Research and Material Command sponsored research, the following statement must be incorporated into the consent form: The United States Department of Defense is funding this research Should you be injured as a direct result of participating in this research

project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

For investigational drug/device studies, the following statement should be included: Other than medical care that may be provided, [and any other remuneration specifically stated in this informed consent], I/you will not receive any compensation for my/your participation in this research study; however, I/you understand that this is not a waiver or release of my/your legal rights.

11. An explanation of (names and telephone numbers)

    a. whom to contact for answers to pertinent questions **about the research** study and in the event of a research-related **injury** to the subject [should be the investigator];

    b. whom to contact for answers to pertinent questions about research subjects' **rights** [should be the IRB or legal office].

12. A statement that participation is **voluntary**, that refusal to participate will involve **no penalty or loss of benefits** to which the subject is otherwise entitled, and that the subject may **discontinue participation** at any time without penalty or loss of benefits to which the subject is otherwise entitled.

13. Provide **space** for date, signature, typed/printed name and permanent address of subject and signature and typed/printed name of witness.

14. The subject and the witness should be instructed to initial and date all but the last page of the consent form.

15. .If the samples donated in this study will be used in other studies, the statement "I understand that there is a possibility that the blood, tissue, body fluid, product, or sample(s) (specify type) which I am providing under this study may also be used in other research studies and could potentially have some commercial applicability." Should be included in the consent form. In addition, **a donation form** must be prepared for signature by the volunteer which states "I voluntarily and freely donate any and all blood, tissues, body fluid, product, or sample(s) (specify type) to the study sponsor (insert institution name) and hereby relinquish all right, title and interest to said items." The title of the study should be inserted at the top of the form. (These samples that will be stored must contain no personal identifiers.)

16. If pregnant women will be excluded, the following statement must be included: "In order to participate in this study, I should have avoided becoming pregnant from the first day of my most recent menses. I should avoid becoming pregnant for at least [time period in days, weeks, or months] after [study end date, receipt of drug, etc.]. Pregnancy within [time period in days, weeks, or months] after [study end date, receipt of drug, etc.] may create a potential risk to the unborn baby. To avoid becoming pregnant, I should either abstain from sexual relations or practice a method of birth control. Except for surgical removal of the uterus, birth control methods such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy. The only ways to completely avoid risk to the unborn baby are (1) to not become pregnant or (2) do not receive this drug. Adverse effects might affect a developing fetus. Further, might result in unknown risks of deformities or death to the unborn baby. A negative pregnancy test does not absolutely prove that your are not pregnant. Regardless of the results of the pregnancy test which you were administered as part of the screening for this study, you should not participate if you think there is a possibility that you might be pregnant. **Also**, a statement should be included which directs the volunteer to notify the principal investigator if she becomes pregnant. If women will be withdrawn from the study if they become pregnant, that should be clearly indicated.

17. Any additional costs to the subject must be clearly indicated.

18. For all studies involving more than minimal risk, the following statement must be included in the consent form: "It is the policy of the U.S. Army Medical Research and Material Command (USAMRMC) that data sheets are to be completed and all volunteer participating in research for entry into the USAMRMC's Volunteer Registry Data Base. The information to be entered into this confidential data base includes your name, address, social security number, study name, and date. The intent of this confidential data base is two fold: first, to readily answer questions concerning an individuals' participation in research sponsored by USAMRMC; and second to ensure that the USAMRMC can exercise its obligation to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.